Election/Restrictions

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 19 and 21, drawn to nucleic acids encoding a polypeptide, vectors, host cells, and recombinant methods of producing a polypeptide, classified in class 435, subclass 69.1+.

II. Claims 9-11, 20 and 22, drawn to a polypeptide, classified in class 530, subclass 350+.

III. Claim 12, drawn to an antibody, classified in class 530, subclass 387.1.

IV. Claim 13-15, drawn to a method of detecting a nucleic acid, classification dependent on structure of recited compound.

V. Claim 16, drawn to a method of detecting a polypeptide in a cell, tissue, or fluid sample, classification dependent on structure of recited compound.

VI. Claims 17 and 18, drawn to a method of detecting a ligand of a polypeptide, classification dependent on structure of recited compound.

Secondary Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Additionally, applicant is required to elect one sequence from: SEQ ID NO: 1-12, 21-40, 43-53, 56-62, and 76-101.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I-III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The nucleic acid of group I can be used in gene therapy as well as in the production of the protein of interest. The protein of Group II can be used to make an antibody, or used therapeutically. The antibody of Group III can be used to detect the polypeptide of Group II, or used as a ligand.

Invention I is related to invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polynucleotide of Group I can be used other than to detect nucleic acids, such as used to recombinantly make proteins.

Invention I is unrelated to inventions V and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP

§ 808.01). In the instant case the polynucleotide of Group I is neither used in nor produced by the methods of Inventions V and VI.

Invention II is unrelated to invention IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of Group II is not used in a method of detecting a polynucleotide.

Invention II is related to inventions V and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide of Group II can be used other than to detect ligands, such as used to generate antibodies.

Invention III is unrelated to inventions IV and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group III is not used in a method of detecting a polynucleotide or detecting an antagonist of a polypeptide.

Invention III may be related to invention V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the antibody of Group III can be used other than to detect a polypeptide, such as used as a receptor antagonist.

Groups IV-VI are distinct from each other because they are drawn to distinct methods which differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. Therefore, they are patentably distinct from each other.

Furthermore, each set of sequences represents a patentably distinct invention. The sequences are independent and distinct, each from the other, because they have different putative functions, different structures, and require completely different search terms, starting points and strategies.

Because these inventions are distinct for the reasons given above and the search required for each group is unique, and because each protein or nucleic acid of the Secondary Restriction requires a completely separate search, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Inventive Groups I through VI, and must additionally elect a SEQ ID NO. Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so**

may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

SLW
5 January 2008

/Manjunath N. Rao, /
Supervisory Patent Examiner, Art Unit 1647